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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF:

*Lee et al.*

SERIAL NO.: 09/499,693

FILED: February 8, 2000

FOR: **HIGHER UNSATURATED FATTY  
ACID COMPOSITION**

EXAMINER: L. Wells

ART UNIT: 1617

CONFIRMATION NO.: 1622

**DECLARATION BY INSU P.LEE**

Commissioner for Patents  
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**RECEIVED**  
DEC 05 2003  
TECH CENTER 1600/2900

Sir:

I, INSU P.LEE, declare:

1. I currently hold the position of Visiting Lecturer at Kanazawa University and CEO, Tri-Life Res. Inc., and have been employed at Tri-Life Res. Inc. since 2000.
2. I received my Ph.D. from School of Medicine University of Wash. in 1971 in Pharmacology.
3. I have been active in the field of Pharmacology for over 40 years. My area of technical expertise is Medical toxicology.
4. I am a named inventor on the above-noted application, and I have read the above-referenced application.

### **The Invention**

5. The present invention requires the following two elements (i) a linoleic/a-linolenic fatty acid weight ratio of 0.05-7.5; and (ii) flaxseed oil. Thus, the "basic and novel characteristic" of the invention is the weight ratio of linolenic fatty acid to a-linolenic fatty acid in the range of 0.05-7.5.

6. Addition of ingredients that contain linoleic fatty acid, a-linolenic fatty acid, or both, in an amount that causes the weight ratio to fall outside the 0.05-7.5 range is a material change to the claimed composition.

7. I have reviewed Leach (U.S. Patent No. 5,612,074), and understand it to disclose a ratio of linoleic fatty acid to a-linolenic fatty acid of 3:1 by weight only for the oil seeds of the mixture of dry ingredients and the vegetable oil of the liquid ingredients. Leach teaches numerous ingredients not included in the oil seeds or vegetable oil of the liquid ingredients that contain linoleic fatty acid, a-linolenic fatty acid, or both. The food bar described in the first preferred embodiment has a linoleic fatty acid to a-linolenic fatty acid weight ratio of at least 8.6. Thus, it is clear that Leach does not consider the linoleic fatty acid to a-linolenic fatty acid weight ratio of the entire food bar.

8. In contrast, the present invention is based on my finding that by adjusting the weight ratio of linoleic fatty acid to a-linolenic fatty acid to 0.05 to 7.5, DHA (docosahexaenoic acid) is synthesized most efficiently, particularly in the brain. DHA synthesis is derived from a-linolenic fatty acid and is shown in our examples to increase the cognitive and learning faculty and the memory. Addition of ingredients that alter the composition's linoleic fatty acid to a-linolenic fatty acid ratio to be outside of this range fail to produce this increase in cognitive and learning faculty and the memory.

9. Thus, it is my professional opinion that the introduction of additional steps or components would materially change the characteristics of applicant's invention.

all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Nov. 3, 2003

Date

  
(inventor's name)